

IAP12 Rec'd PCT/PTO 01 MAY 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ludmerer, Steve W. et al.

Serial No. To Be Assigned

Art Unit: _____

Filed:

Examiner: _____

For: HCV REPLICONS CONTAINING NS5B FROM
GENOTYPE 2BCommissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

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MERCK & CO., INC.

By _____ Date _____

10/577893
PATENT Case No. 21564YP
IAP12 Rec'd PCT/P10 J1 MAY 2006

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

the attached information is filed within three months of the filing date of the captioned case.

the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.

the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).

each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.

each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*

no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Sheldon O. Heber

Attorney _____ For Applicant(s)

Reg. No. 38,179

MERCK & CO., INC.

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Date: May 1 2006

<p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE</p> <p>STATEMENT BY APPLICANT</p> <p><i>(use as many sheets as necessary)</i></p>				<p style="text-align: center;">COMPLETE IF KNOWN</p> <p>17577875</p> <p>Application Number 10/12 Rec'd PCT/PTO 01 MAY 2006</p> <p>Filing Date</p> <p>First Named Inventor Ludmerer, Steven W. et al.</p> <p>Group Art Unit</p> <p>Examiner Name</p>	
Sheet	1	of	3	Attorney Docket Number	21564YP

Examiner Signature _____ Date Considered _____

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INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

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Sheet

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of

3

Application Number **1A12 Rec'd PCT/PTO J 1 MAY 2006**

Filing Date

First Named Inventor

Ludmerer, Steven W. et al.

Group Art Unit

Examiner Name

Attorney Docket Number **21564YP**

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Bartenschlager, R. "Hepatitis C virus replicons: potential role for drug development", Nature Reviews, 2002, Vol. 1, pp. 911-916
		Bartenschlager, R. et al. "Nonstructural Protein 3 of the Hepatitis C Virus Encodes a Serine-Type Proteinase Required for Cleavage at the NS3/4 and NS4/5 Junctions", Journal of Virology, 1993, Vol. 67, pp. 3835-3844
		Behrens, S. et al. "Identification and properties of the RNA-dependent RNA polymerase of hepatitis C virus", The EMBO Journal, 1996, Vol. 15, pp. 12-22
		Blight, K. et al. "Efficient Initiation of HCV RNA Replication in Cell Culture", Science, 2000, Vol. 290, pp. 1972-1974
		Carroll, S. et al. "Inhibition of Hepatitis C Virus RNA Replication by 2'-Modified Nucleoside Analogs", The Journal of Biological Chemistry", 2003, Vol. 278, pp. 11979-11984
		Choo, Q. et al. "Isolation of a cDNA Clone Derived from a Blood-Borne Non-A, Non-B Viral Hepatitis Genome", Science, 1989, Vol. 244, pp. 359-362
		Farci, P. et al. "Clinical Significance of Hepatitis C Virus Genotypes and Quasispecies", Seminars in Liver Disease", 2000, Vol. 20, pp. 103-126
		Grakoui, A. et al. "A second hepatitis C virus-encoded proteinase", Proc. Natl. Acad. Sci. USA, 1993, Vol. 90, pp. 10583-10587
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		Grobler, J. et al. "Identification of Key Determinant of Hepatitis C Virus Cell Culture Adaptation in Domain II of NS3 Helicase", The Journal of Biological Chemistry, 2003, Vol. 278, pp. 16741-16746
		Hijikata, M. et al. "Proteolytic processing and membrane association of putative nonstructural proteins of hepatitis C virus", Proc. Natl. Acad. Sci. USA, 1993, Vol. 90, pp. 10773-10777
		Ikeda, M. et al. "Selectable Subgenomic and Genome-Length Dicistronic RNAs Derived from an Infectious Molecular Clone of the HCV-N Strain of Hepatitis C Virus Replicate Efficiently in Cultured Huh7 Cells", Journal of Virology, 2002, Vol. 76, pp. 2997-3006
		Krieger, N. et al. "Enhancement of Hepatitis C Virus RNA Replication by Cell Culture-Adaptive Mutations", Journal of Virology, 2001, Vol. 75, pp. 4614-4624
		Kuo, G. et al. "An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non-B Hepatitis", Science, 1989, Vol. 244, pp. 362-364
		Lohmann, V. et al. "Biochemical and Kinetic Analyses of NS5B RNA-Dependent RNA Polymerase of the Hepatitis C Virus", Virology, 1998, Vol. 249, pp. 108-118

Examiner Signature	Date Considered
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INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

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Application Number	1412 Rec'd PCT/PTO 31 MAY 2006
Filing Date	
First Named Inventor	Ludmerer, Steven W. et al.
Group Art Unit	
Examiner Name	

Sheet 3 of 3 Attorney Docket Number 21564YP

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Lohmann, V. et al. "Mutations in Hepatitis C Virus RNAs Conferring Cell Culture Adaptation" Journal of Virology, 2001, Vol. 75, pp. 1437-1449
		Lohmann, V. et al. "Replication of Subgenomic Hepatitis C Virus RNAs in a Hepatoma Cell Line", Science, 1999, Vol. 285, pp. 110-113
		Lohmann, V. et al. "Viral and Cellular Determinants of Hepatitis C Virus RNA Replication in Cell Culture", Journal of Virology, 2003, Vol. 77, pp. 2007-3019
		Love, R. et al. "Crystallographic Identification of a Noncompetitive Inhibitor Binding Site on the Hepatitis C Virus NS5B RNA Polymerase Enzyme", Journal of Virology, 2003, Vol. 77, pp. 7575-7581
		Mizushima, H. et al. "Analysis of N-Terminal Processing of Hepatitis C Virus Nonstructural Protein 2", Journal of Virology, 1994, Vol. 68, pp. 2731-2734
		Murray, E. et al. "Persistent Replication of Hepatitis C Virus Replicons Expressing the B-Lactamase Reporter in Subpopulations of Highly Permissive Huh7 Cells", Journal of Virology, 2003, Vol. 77, pp. 2928-2935
		Pawlotsky, J. et al. "Hepatitis C virus (HCV) NS5A protein; role in HCV replication and resistance to interferon α ", Journal of Viral Hepatitis", 1999, Vol. 6, pp. 47-48
		Pietschmann, T. et al. "Characterization of Cell Lines Carrying Self-Replicating Hepatitis C Virus RNAs", Journal of Virology, 2001, Vol. 75, pp. 1252-1264
		Takamizawa, A. et al. "Structure and Organization of the Hepatitis C Virus Genome Isolated from Human Carriers", Journal of Virology, 1991, Vol. 65, pp. 1105-1113
		Tomei, L. et al. "Mechanism of Action and Antiviral Activity of Benzimidazole-Based Allosteric Inhibitors of the Hepatitis C Virus RNA-Dependent RNA Polymerase", 2003, Vol. 77, pp. 13225-13231
		Tomei, L. et al. "NS3 Is a Serine Protease Required for Processing of Hepatitis C Virus Polyprotein", Journal of Virology, 1993, Vol. 67, pp. 4017-4026
		Vrolijk, J. et al. "A replicon-based bioassay for the measurement of interferons in patients with chronic hepatitis C", Journal of Virological Methods, 2003, Vol. 110, pp. 201-209
		Wang, M. et al. "Non-nucleoside Analogue Inhibitors Bind to an Allosteric Site on HCV NS5B Polymerase", The Journal of Biological Chemistry, 2003, Vol. 278, pp. 9489-9495

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